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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CLARK, AMY LYNN	
ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
09/12/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/642,596	MAY ET AL.	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8,9,11,12 and 14-23* is/are pending in the application.

4a) Of the above claim(s) *11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8,9,12 and 14-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Office Action mailed out on 04/21/2008 has been vacated and the following Office Action replaces the previous Office Action in its entirety.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Claims 1, 8, 9, 11, 12 and 14-23 are currently pending.

Claims 8 and 12, which were previously withdrawn from consideration under 37 CFR 1.142, have been rejoined, **the restriction requirement between these two inventions as set forth in the Office action mailed on 03/26/2007 is hereby withdrawn; however, the product as claimed in claim 11 remains withdrawn for the reasons set forth in the previous Office Action.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim 11 remains withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or

linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 03/26/2007.

Claims 1, 9, 12 and 14-23 are currently under examination.

Claim Objections

Please note that throughout the claims, coordinating conjunctions are missing. Below are some examples of places that coordinating conjunctions are missing; however, Applicants should look through the claims and insert any other coordinating conjunctions, where appropriate.

Claim 1 is objected to because of the following informalities: In line 4, make the following correction: "(a)". In line 3, insert the after "of", in line 4, insert the before "of", in line 5, insert a at the beginning of the line and make the following correction to line 5: "phytonutrients". In line 6, insert the after "of" and make the following corrections to line 6: "phytonutrients" and "(b)". Please make similar corrections to claim 12, where appropriate. Claim 12 should also be corrected to include a at the beginning of lines 4, 7 and 9, before "with" in line 18 and before "and" in line 19. Appropriate correction is required.

Claims 1 and 12 are objected to because of the following informalities: The way the steps are labeled a), b), c), in claim 1 and i., ii., iii., in claim 12 are inconsistent. It is suggested that the steps be labeled in a consistent manner (either both utilizing the alphabet or both using Roman numerals). Furthermore, the method steps should be indented, as demonstrated here:

"A method of extraction of phytosterols, squalene and vitamin E from crude palm oil comprising the steps of:

a) conversion of crude palm oil into palm oil methyl esters;

b) three short path distillation of the crude palm oil methyl esters obtained in step a) to yield a phytonutrient concentrate;..."

Appropriate correction is required.

Claims 8, 14 and 21 are objected to because of the following informalities: In claim 8, line 2, insert a after "with" and after "solvent," and "the" after "crystallize" in line 4. In claim 14, line 1, insert a after "wherein" in line 1 and after "and" in line 1 bridging line 2. In claim 21, line 2, insert a after "with" and after "and" in line 3. Appropriate correction is required.

Claims 8, 9 and 14-23 are objected to because of the following informalities: In the first line of each claim, please delete "A" and insert The before the term "method". Appropriate correction is required.

Claim 9 is objected to because of the following informalities: in line 1, insert the after "hydrocarbon" and after "to," in line 2. Appropriate correction is required.

Claim 14 is objected to because of the following informalities: in line 1, insert a after "wherein" and after "and" in line 1 bridging line 2. Appropriate correction is required.

Claim 16 is objected to because of the following informalities: Please correct as follows: "The A method as claimed in claim 1, wherein the three path distillation in step (b) ~~proceeds as follows~~ further comprises the following steps

-a short path distillation is carried out on the crude palm oil methyl esters;

-a second stage short path distillation is carried out on the residue of the first stage short path distillation;

-a third stage short path distillation is carried out on a residue of the first stage short path distillation".

Please note that the Examiner has not corrected the 112 2nd issues mentioned below, but rather has provided a template for the way the claim should be structured. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1, 8, 9, 12 and 14-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "crude palm oil" in claims 1 and 12 is a relative term which renders the claim indefinite. The term "crude palm oil" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The metes and bounds of claim 1 are rendered uncertain by the phrase "three short path distillation" and "c) saponification of the phytonutrient concentrate from step (b); crystallization of phytosterols; e) solvent partitioning of vitamin E and squalene". With regards to "three short path distillation" does Applicant mean that there are three short path distillations or that the process is called "three short path distillation"? The

way the step is written, it is unclear as to whether three distillations are carried out or just one. With regards to "c) saponification of the phytonutrient concentrate from step b); crystallization of phytosterols; e) solvent partitioning of vitamin E and squalene" it is unclear where the phytosterols, vitamin E and squalene are from, since none of the preceding steps indicate the presence of any of these compounds. For example, if the phytonutrient concentrate contains these compounds, then this should be reflected in that step or in the claims. It is also important that all of the steps are tied together; therefore, a coordinating conjunction (for example: and) should be inserted between the final two lines. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of claim 8 are rendered uncertain by the phrase "and heated to a temperature of 65 ºC to 85 ºC and slowly cooled" because it is unclear as to what is being heated and what is being cooled. It is also unclear as to what "of ratio 25:1:1" means. Is Applicant referring to the ratio of hydrocarbon solvent, a short chain alcohol and water? Furthermore, with regards to the ratio, the claim is unclear because the amounts of the ingredients are not set forth in terms of either 'by weight" or "by volume" amount of the total composition In both cases, if Applicant is referring to the mixture of a hydrocarbon solvent, a short-chain alcohol and water, then this should be reflected in the claim. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claim 9 are rendered uncertain by the phrase "wherein the ratio of the hydrocarbon solvent to the short chain alcohol used to partition the

squalene and the vitamin E is 5:3" because the amounts of the ingredients are not set forth in terms of either 'by weight" or "by volume" amount of the total composition. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claim 12 recites the limitation "the residue" in line 7, "the distillate" in line 9, "the residue" in line 9, "the unsaponifiable matter" in lines 10 and12, "the saponified product" in line 10, "the mixture" in lines 14 and 15, "hydrocarbon layer" in line 17 and "alcohol layer" in line 18. There is insufficient antecedent basis for these limitations in the claim.

Claims 14 and 15 recite the limitation "hexane layer" and "methanol layer" in line 1, bridging line 2 of claim 14 and in line 2 of claim 15. There is insufficient antecedent basis for this limitation in these claims.

Claims 16 and 19 recite the limitation "unsaponifiable matter" in lines 1 and 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 20 recites the limitation "the unsaponifiable matter" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 21 recites the limitation "the mixture" in line 1, "hydrocarbon solvent" in line 3 and "alcohol layer" in line 4. There is insufficient antecedent basis for this limitation in the claim.

The metes and bounds of Claim 23 are rendered uncertain by the phrase "wherein the crude palm oil is converted directly into palm oil methyl esters" because this is the direct result of esterification and transesterification. Since claim 1 recites the first step of the method as converting crude palm oil into palm oil methyl esters, this

would be a direct conversion. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claim Rejections - 35 USC § 103

Claims 1, 8, 9 and 12 and 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nitsche (F, US Patent Number: 5,902,890), in view of Hunt (G, US Patent Number: 5,646,311) and Hirata (O*, JP 09-176057 A).

Nitsche teaches a method of obtaining carotene from palm oil comprising the steps of catalytically reacting palm oil with methanol through a process of transesterification, distilling the ester phase of the reaction mixture by short path evaporation (molecular evaporation), wherein the distillation step may occur over one, two or more stages by reducing the pressure over each stage, and saponifying the distillation residue (See column 2, lines 56-67 and column 4, lines 19-36). Nitsche further teaches that the distillation step may be carried out at a temperature in the range of 120 to 150 °C and may be at a pressure range of 1 to 50 mbar or 10^{0}-10^{-4} mbar for the first distillation and in a range of 10^{0}-10^{-4} mbar for the final stages of distillation (See column 4, lines 19-36), which reads on the range claimed by Applicants. Nitsche further teaches an extraction step following saponification, wherein water is added to the distillation residue in an amount of up to 5 times the volume of the quantity by weight of the distillation residue to help improve solubility behavior in the extraction (See column 4, lines 40-47). Nitsche further teaches that the residue is further mixed with a solvent

mixture containing a non-polar and a polar solvent, wherein the non-polar solvent is a linear or branched hydrocarbon containing 5-12 carbon atoms (See column 4, lines 50-61). Nitsche teaches that the non-polar solvent may be n-hexane and the polar solvent may be acetone (See column 5, "Example"); however, Nitsche further teaches that other solvents are possible as either the non-polar or polar solvent (See column 4, line 61).

Please note that although Nitsche does not expressly teach the separation of phytosterols, tocopherols and squalene from palm oil; however, Nitsche teaches the instantly claimed method steps, in the order claimed by Applicant and using the same apparatus, solvent system, temperature and pressure ranges also claimed by Applicant. Therefore, the method taught by Nitsche intrinsically provides the separation of components from palm oil. Furthermore, Hunt teaches the same method steps as Nitsche including the step of crystalliazion to provide a method of recovering tocopherols, squalene and phytosterols, as set forth below.

Nitsche does not teach methanol as the polar solvent nor does Nitsche teach crystallization; however, Hunt teaches a method of recovering tocopherols, wherein the tocopherols may be obtained from palm oil (See column 1, lines 39-46) comprising the steps of esterification, distillation, optional saponification (See column 11, lines 34-38) and separation of the tocopherols from the sterol compounds using a solvent mixture of water, hexane and methanol, wherein the ratio of methanol to water ranges from 5:1 to 1:5 or 3:1 to 1:3 and comprised of a major amount of the hexane, wherein the hexane is present in an amount of greater than 50% by weight of the solvent blend (See column

11, lines 55-63 bridging column 12, lines 16-47). Hunt further teaches that the solvent blend can be heated to the atmospheric boiling temperature of the blend and then the solvent can be cooled to less than 25° C in increments of 80° C per hour or increments of 2.5-10° C/hour (See column 12, lines 48-65). Hunt further teaches that the sterols crystallize or precipitated to form a solid phase that can be physically separated from the liquid phase by filtration, centrifugation or decanting (See column 12, lines 66 and 67 bridging column 13, lines 1-9).

Nitsche does not teach squalene is recovered in hexane; however, the solvent system taught by Nitsche and Hunt is one and the same as that claimed by Applicants. Therefore, squalene would intrinsically be obtained in the hexane layer of the solvent system. Furthermore, Hirata teaches a method of obtaining squalene from palm oil comprising mixing a vegetable oil and fat containing squalene, or a deacidified and deodorized distillate thereof, with an organic solvent (See abstract). Hirata further teaches that squalene is obtained as a distillate along with other unsaponifiabl\e components, such as hydrocarbons, sterols, and tocopherol (See paragraphs 0005 and 0007). Hirata further teaches that a vegetable squalene concentrate can be manufactured by carrying out hydrogenation of a deacidified and deodorized distillate of palm oil by removing an impurity and condensing squalene (See paragraph 0010), which reads on saponification, and that the method provides a greater amount of squalene recovered if urea or thiourea is used (See paragraph 0012). Hirata further teaches that a ketone system, alcoholic system and hydrocarbon system, can be used as an organic solvent, although alcohol is desired (C_1-C_4).

Therefore, at the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method taught by Nitsche et al. to provide the instantly claimed invention by employing methanol as a solvent in the three solvent system of a polar and non-polar solvent and water and to employ the step of crystallization because at the time the invention was made, the method steps as claimed by Applicant of first converting crude palm oil into palm oil methyl esters, performing three short path distillation at the temperature and pressure claimed, saponification, crystallization of phytosterols and solvent partitioning of vitamin E and squalene, was known, as was the claimed solvent system and the ratio of the solvents, as claimed by Applicant. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method steps for their known benefit in providing tocopherols, phytosterols and squalene since each claimed process step is well known in the art for the same purpose.

From the teachings of the references, it is apparent that one of ordinary skill in the art one would have been motivated to use methanol in the three solvent system as the polar solvent for the expected benefit extracting phytosterols, tocopherols and squalene from palm oil because at the time the invention was made, the instantly claimed solvents were known to be useful for extracting phytosterols, tocopherols and squalene from palm oil since and to employ the method step of crystallization as an additional method step in the order claimed by Applicant because the solvent system for extracting the claimed components of palm oil and the step of crystallization of phytosterols after saponification of the distillate after conversion of palm oil into palm oil

methyl esters were known in the art at the time the invention was made. Thus the combination of hexane with ethanol and water would have been expected to be even more effective for extracting phytosterols, tocopherols and squalene from palm oil because the claimed solvents were all useful for this purpose and crystallization of phytosterols would have also been expected to be even more effective method of separation the desired components from palm oil, as clearly taught by the above references.

Finally, one of ordinary skill in the art would have had a reasonable expectation of success to combine the following solvents to gain the benefits of individual components as part of a method of extracting phytosterols, tocopherols and squalene from palm oil: hexane, methanol and water, to provide a beneficial method for the expected benefit of extracting phytosterols, tocopherols and squalene from palm oil and to add the step of crystallization because at the time the invention was made, these components were well known to be found in palm oil, the method steps were known in the order claimed by Applicants and all of the claimed solvents were known to be combinable to provide the instantly claimed solvent system.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments, see Applicant Arguments/Remarks Made in an Amendment, filed 10/11/2007 and 05/29/2008, with respect to the rejection(s) of claims 1, 9 and 14-22 under 35 U.S.C. 103(a) as being unpatentable over Fizet (D*, US Patent Number 5,487,817), in view of Willging (E*, US Patent Number 4,550,183), Hattori (N*, WO 01/32682 A1) and Hirata et al. (O*, JP 09-176507 A, Translation provided herein). have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made of claims 1, 8, 9 and 12 and 14-23 under 35 U.S.C. 103(a) as being unpatentable over Nitsche (F, US Patent Number: 5,902,890), in view of Hunt (G, US Patent Number: 5,646,311) and Hirata (O*, JP 09-176057 A).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571)272-1310. The examiner can normally be reached on Monday to Friday between 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark
AU 1655

Amy L. Clark
September 1, 2008

/Michele Flood/
Primary Examiner, Art Unit 1655